## **REMARKS/ARGUMENTS**

This is in full and timely response to the non-final Office Action mailed November 3, 2003, submitted concurrently with a Petition to Extend Time to within the first extended month.

No claims have been amended, and the examiner is asked to reconsider the rejections in view of the following remarks. Claims 1 and 3-6 are pending in this application, with claim 1 being independent. Applicants believe that at least claims 1 and 3-6 are in condition for allowance. Reexamination and reconsideration in light of the above amendments and the following remarks is respectfully requested.

## Rejections under 35 U.S.C. §103

Claims 1 and 3, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,603,315 to Sasso, Jr. in view of U.S. Patent 6,401,713 to Hill et al. Applicants respectfully traverse this rejection.

Claim 1 is directed to an apparatus for supplying an oxygen therapeutic gas and includes a cylinder, a nasal cannula, a conduit, a pressure sensor, a valve and a controller. Claim 1 recites an apparatus for supplying as oxygen therapeutic gas, comprising: a cylinder for containing a pressurized oxygen therapeutic gas; a nasal cannula, adapted to be introduced into a nasal passage of a patient; a conduit extending between the cylinder and the nasal cannula for directing the oxygen therapeutic gas to the nasal cannula from the cylinder; a valve, provided on the conduit, for allowing and blocking the fluid communication between the cylinder and the nasal cannula; a pressure sensor, provided on the conduit downstream of the valve, for detecting the pressure in the conduit; an orifice, provided on the conduit upstream of the valve, for regulating pressure in the conduit upstream of the valve; and a controller for controlling the operation of the valve in synchronization with respiration of a patient based on changes in pressure detected by the pressure sensor, the controller comparing respiratory frequency with a threshold to increase volume of the oxygen therapeutic gas for each respiration in step when the respiratory frequency is larger than the threshold.

As discussed during the Personal Interview, inclusion of an additional limitation to claim 1, specifically, that the claiming of an orifice upstream of the valve would overcome the applied art rejections.

Sasso '315 discloses a multiple mode oxygen delivery system for pulse dosing and conservation of oxygen in a delivery system. The main object of Sasso '315 is to provide an oxygen delivery system improved to continually adjust the oxygen pressure to provide an accurate output despite inaccuracies induced by conventional regulators and pressure changes due to oxygen tank consumption. For this purpose, the pressure sensor 6 is coupled to the line 12 between the pressure regulator 4 and the restrictor 16, that is upstream of the valve 18, so as to detect the output pressure of the gas source 2.

As acknowledged in the Office Action, Sasso '315 does not disclose, teach or suggest an orifice, provided on the conduit upstream of the valve, for regulating pressure in the conduit upstream of the valve.

The Office Action alleges that that Hill et al. '713 discloses an orifice 48 upstream of the valve. This is incorrect. Hill et al. '713 discloses an orifice 48 **DOWNSTREAM** of the valve. This is no different that the previous acknowledgement that Freitag et al. '812 disclose an orifice downstream of any valves. Hill et al. '713 do not disclose, teach or suggest an orifice, provided on the conduit upstream of the valve, for regulating pressure in the conduit upstream of the valve.

Accordingly, all of the claimed elements must be disclosed, taught or suggested in the combined references in a §103 rejection. Discussing the references individually to show the lack of recited elements is proper and necessary, because if all of the claimed elements are not disclosed, taught or suggest, then de facto the combination of the references do not rise to a prima facie level of obviousness.

Accordingly, neither Sasso '315 nor Hill et al. '713 disclose, teach or suggest the recited claim elements, either alone or in combination. Accordingly, a prima facie case of obviousness has not been established. Withdrawal of this rejection is respectfully requested.

Still further, merely substituting Hill et al. '713 for the previously applied Freitag et al. '812 for the element of an orifice upstream of the valve, instead of a Notice of Allowance, is an unnecessary delay in prosecution, and ignores the outcome of the September personal interview.

Still further, Sasso '315 describes that "Oxygen delivery is based on a fixed volume of oxygen per breath which provides the advantage of a varying net volume being delivered to the patient per period of time depending on and proportional to their respiratory rate. Thus, if a patient exercises and their breathing rate increases, the control circuit will automatically and proportional to the breathing rate, and increase the net volume of oxygen being delivered." Column 3, lines 17-24, emphasis added. Therefore, in Sasso '315, microcontroller 8 does not compare "respiratory frequency with a threshold to increase volume of the oxygen therapeutic gas for each respiration in step when the respiratory frequency is larger than the threshold."

Still further, Hill et al. '713 describes that "More specifically, the controller causes the gas flow generating system to provide a continuous flow of breathing gas to the patient at a first pressure level P1 in an initial therapy session. Thereafter, the controller automatically causes the gas flow generating system to increase the pressure level of the continuous flow of breathing gas to a final pressure level P2 over a first predetermined number D of days." See column 1, line 63 to column 2, line 3 (emphasis added). Therefore, in the invention of Hill et al. '713, controller 40 does not compare "respiratory frequency with a threshold to increase volume of the oxygen therapeutic gas for each respiration in step when the respiratory frequency is larger than the threshold."

Accordingly, Hill et al. '713 does not make up for the deficiencies of Sasso '315, and a prima facie case of obviousness has not been established. Withdrawal of this rejection is requested.

Dependent claims 3, 5 and 6 being dependent upon allowable claim 1, are also allowable for the reasons above. Moreover, these claims are further distinguished by the additional features recited therein, particularly within the claim combination.

Accordingly, withdrawal of the §103 rejections is respectfully requested.

Claim 4 is rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Patent No. 5,603,315 to Sasso, Jr. in view of U.S. Patent No. 5,865,174 to Kloeppel. Applicants respectfully traverse this rejection.

Kloeppel '174 describes that "a controller in operative connection with said pressure sensor and said valve, wherein said controller is operative to cause said valve to change from the first condition to the second condition responsive to said senses pressure reaching a threshold level." See claim 1 (emphasis added). Therefore, in the invention of Kloeppel '174, microcontroller 64 does not

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compare "respiratory frequency with a threshold to increase volume of the oxygen therapeutic gas for each respiration in step when the respiratory frequency is larger than the threshold."

Accordingly, Kloeppel '174 does not make up for the deficiencies of Sasso '315, and a prima facie case of obviousness has not been established. Withdrawal of this rejection is requested.

Dependent claim 4 depending from claim 1 is also allowable for the reasons above. Moreover, this claim is further distinguished by the materials recited therein, particularly within the claimed combination. Withdrawal of the §103(a) rejection is therefore respectfully solicited.

## **Conclusion**

For the foregoing reasons, claims 1 and 3-6 are allowable, and the present application is in condition for allowance. Accordingly, favorable reexamination and reconsideration of the application in light of these amendments and remarks is courteously solicited. If the examiner has any comments or suggestions that would place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number below.

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Respectfully submitted,

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